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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,041	05/06/2004	Fabrizio Alessandro Maspero	1032553-000059	7765
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EXAMINER RAMANA, ANURADHA				
ART UNIT 3775		PAPER NUMBER		
NOTIFICATION DATE 12/29/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

# Office Action Summary

**Application No.**

10/840,041

**Applicant(s)**

MASPERO ET AL.

**Examiner**

Anu Ramana

**Art Unit**

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 41-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 41-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/2009 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 16, 47-50, and 56-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation " a biocompatible polymer coating at least....." renders the claim vague and indefinite since the phrase is runon and does not clearly recite where the coating is.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41, 43-45, 55, 63 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (US 7,241,316).

Evans et al. disclose a moldable implant composition including: a plurality of biocompatible synthetic non-bone particles such as ceramics or calcium phosphate or calcium sulfate having a particle size of about 100 microns; a biocompatible polymer such as polylactide or polycaprolactone; a plasticizer such as caprolactone; and a biologically active substance such as a growth factor wherein the composition can be delivered by injection or preformed as an implant for surgical insertion (Figs. 15-18, col. 16, lines 20-61, col. 18, lines 63-67, col. 19 and col. 20, lines 1-51).

Regarding claim 55, it is noted that Evans et al. discloses particles having a particle size of about 100 microns, i.e., regularly-sized particles.

Regarding claims 63 and 64, it is noted that Evans et al. discloses a specific value of particle size of about 100 microns, which is within the claimed ranges of "of about greater than 10 microns to about 2000 microns" and "of about 100 microns to about 500 microns". It is noted that a specific example in the prior art which is within a claimed range anticipates the range. MPEP 2131.03.

Claims 43-45, 55, 63 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Ricci et al. (US 6,770,695).

Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides, polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5 microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47). Once solidified in a bone defect, the Ricci et al. composition forms a composite matrix with pores filled with air.

Regarding claim 55, it is noted that Ricci et al. disclose particles having a size (underline, emphasis added) greater than 20 microns, i.e., regularly-sized particles.

Regarding claims 63 and 64, it is noted that Ricci et al. discloses a specific value of particle size, i.e., a size greater than 20 microns, which is within the claimed ranges "of about greater than 10 microns to about 2000 microns" and "of about 100 microns to about 500 microns". It is noted that a specific example in the prior art which is within a claimed range anticipates the range. MPEP 2131.03.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-9, 11-12, 16, 41-42, 46-54 and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. (US 6770695).

Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides, polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5 microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47).

Ricci et al. disclose particles with a size greater than 20 microns. Ricci et al. also disclose the weight of the polymer to be about 0.1% to about 50% by weight.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided particles with sizes in a range of about 100 microns to about 4000 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided polymer in a range of about 4% to about 20% by weight, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a polymeric coating thickness in a range of about 1 micron to about 300 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Evans et al. (US 7,241,316).

Ricci et al. disclose all elements of the claimed invention except for alternate types of biocompatible ceramics.

Evans et al. teach the use of biocompatible ceramics such as various calcium phosphate salts (col. 20, lines 21-51).

The substitution of one known ceramic (various types of calcium phosphate) for another known ceramic (calcium sulfate as disclosed by Ricci et al.) would have been obvious to one of ordinary skill in the art at the time of the invention since this amounts to simple substitution of one known ceramic for another and would have yielded predictable results, namely, a biocompatible, implantable composition.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Meredith (US 7,001,551).

Ricci et al. disclose all elements of the claimed invention except for a biologically active substance.

It is well known to use a biologically active substance such as a growth factor in an implantable composition to enhance bone growth into a bone defect, as evidenced by Meredith (col. 9, lines 53-67 and col. 10, lines 1-26).

Therefore, it would have been recognized by one of ordinary skill in the art that applying the known technique of providing a biologically active substance such as a growth factor, taught by Meredith, in the Ricci et al. implantable composition would have yielded predictable results, i.e., improved repair of a bone defect by enhancing bone growth to seal the defect.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Smestad (US 4430760).

Ricci et al. disclose all elements of the claimed invention except for the use of a microporous membrane.

It is well known to use a porous casing or membrane to contain filling material used to repair a bone defect, as evidenced by Smestad (col. 2, lines 57-68 and col. 3, lines 1-57).

Therefore, it would have been recognized by one of ordinary skill in the art that applying the known technique of providing a porous casing, as taught by Smestad, to hold the Ricci et al. material would have yielded predictable results, i.e., containment having a desired shape and size for sealing a bone defect.

Claim 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US 7241316).

Evans et al. disclose all elements of the claimed invention except for the claimed weight percentage of the biocompatible polymer to be about 4% to about 20%.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the claimed weight percentages of biocompatible polymer, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments have been fully considered by the examiner but are not persuasive for the following reasons.

Regarding the rejections under 35 U.S.C. 102(e) over Evans et al., it is noted that Evans et al. discloses pores having a size ranging from 25 microns to 1000 microns. Although Evans et al. do not explicitly disclose a coating, it is the Examiner's position that the particles of Evans et al. are coated with polymer when the non-polymeric granules are mixed with polymer and the plasticizer.

Regarding the rejections under 35 U.S.C. 102(e) over Ricci et al., it is noted that Ricci et al. has a structural matrix that is formed by granules bound together, at least, in part, (underline, emphasis added) by a biocompatible polymer coating formed on each granule. Regarding, the limitation "an open porous region comprising macropores," the Ricci et al. composite matrix, after implantation, meets this limitation (see for e.g., Fig. 3).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
December 19, 2009

/Anu Ramana/  
Primary Examiner, Art Unit 3775